

REMARKS

Claims 1, 3, 12-16, 18-24 have been amended. Claims 26-32 are new. Claims 2 and 25 have been canceled. Support for the new and amended claims can be found throughout the specification, for example, in Figure 1 and corresponding portions of the specification. In addition, new claim 32 is identical to the previously-pending version of claim 1.

Claim Rejections – 35 U.S.C. §103

Claims 1-3, 12-16 and 18-24 were rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 5,360,414 (Yarger).

Claim 1, as amended, recites “an access member including an outer wall defining an internal lumen, the access member having a longitudinal axis and proximal and distal ends . . . the outer wall defining a window through an entire thickness of the outer wall in a radial direction, wherein the window is adjacent the distal end and in communication with the internal lumen and has a radial arc ranging from about 90 degrees to about 180 degrees around the longitudinal axis, the outer wall defining a slot through the entire thickness of the outer wall in the radial direction, wherein the slot extends from the window to the distal end of the access member and has a radial arc around the longitudinal axis that is smaller than the radial arc of the window.”

An example of the claimed subject matter is shown in Figure 1 of the present application, which shows a device 10 with an access member 12 that has an outer wall 14 defining an internal lumen 16. The access member having a longitudinal axis “ α ”, a proximal end 18 and a distal end 20. The outer wall 14 defines a window 24 through an entire thickness of the outer wall 14 in a radial direction. The window 24 is adjacent the distal end 20 and in communication with the internal lumen 16. The window 24 has a radial arc that is between about 90 degrees and 180 degrees around the longitudinal axis. The outer wall 14 also defines a slot 26 through the entire thickness of the outer wall 14 in the radial direction. The slot 26 extends from the window 24 to

the distal end 18 of the access member 14 and has a radial arc around the longitudinal axis that is smaller than the radial arc of the window 24.

As discussed below, Yarger does not disclose or render obvious the subject matter now recited in claim 1.

Yarger discloses a suction tube assembly 40 that includes a perforated suction tube 42, a connector 44 and an outflow tube 46. *See* Figure 6. The perforated suction tube 42 defines an interior bore 30 and has external surface features that define external lumens 26. The external lumens 26 communicate with the region surrounding the perforated suction tube 42 through longitudinal entrance channels 32 (*see* Figure 9). The perforated suction tube 42 also has a plurality of spaced apart holes 28. The distal tip end 31 of the perforated suction tube 42 is rounded and sealed. In use, the perforated suction tube 42 is inserted into the body, for example, through the nose, down the throat and into the stomach for removing fluids and other matter therefrom. (6: 44-54). Body fluid may be drawn into the interior 30 of the perforated suction tube 42 directly through holes 28 by a vacuum source (not shown). (6:55-7:2).

Yarger indicates that a problem with known nasogastric suction tubes is that the organ walls or body tissue, e.g., interior stomach lining, may collapse around the holes 28 thus closing them off. However, with Yarger's perforated suction tube 42, the body fluid may also enter into the exterior lumens 26 through the entrance channels 32 anywhere along the length of the channels and then travel along the external lumens 26 until reaching one of the holes 28 whereupon the fluid can enter the interior 30 of the perforated suction tube 42. The entrance channels 32 are sufficiently narrow to prevent the stomach lining or other tissue, and debris, from entering the external lumens 26. Thus, Yarger explains, the external lumens 26 will not be closed off by body tissue or debris.

Yarger's external lumens 26 do not extend "through an entire thickness of the outer wall in a radial direction," as now recited in claim 1. Instead, the external lumens 26 extend only partially through the perforated suction tube 42. *See* Figure 9.

Nor would a person of ordinary skill have had any reason to modify Yarger's external lumens 26 to produce the claimed subject matter. As discussed above, during use, body fluid

may enter the exterior lumens 26 through the entrance channels 32 anywhere along their length and then travel along the external lumens 26 until reaching one of the holes 28 whereupon the fluid can enter the interior 30 of the perforated suction tube 42. A person of ordinary would have recognized that modifying the external lumens 26 to make them extend through an entire thickness of the perforated suction tube 42 in a radial direction would have rendered them ineffective for their intended use. The person of ordinary skill, therefore, not only would have considered such a modification to be non-obvious, but, in fact, undesirable.

The applicant submits that claim 1, as amended, is allowable for at least the foregoing reasons.

Claims 2-3, 12-16, 18 and 19 depend from claim 1 and, therefore, are allowable for at least the same reasons as claim 1.

Claims 20-23 also were rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 5,360,414 (Yarger).

Claim 20 recites subject matter that is similar to the subject matter recited in claim 1, discussed above. More particularly, claim 20 recites "an elongated access member . . . having a proximate end, a distal end and an outer wall defining a longitudinal bore extending the length of the access member; the outer wall having a window communicating with the longitudinal bore, the window having a radial arc in the range of about 90 degrees to about 180 degrees around a longitudinal axis of the access member, wherein the window extends through an entire thickness of the outer wall in a radial direction; the outer wall having a slot communicating with the longitudinal bore and extending from the window to the distal end approximately parallel to the longitudinal axis of the access member, wherein the slot extends through the entire thickness of the outer wall in the radial direction and defines a radial arc around the longitudinal axis that is smaller than the radial arc of the window."

For similar reasons as those discussed above with reference to claim 1, Yarger does not disclose or render obvious the claimed subject matter.

Claim 20 is allowable for at least the foregoing reasons.

Claims 21-23 depend from claim 20 and, therefore, are allowable for at least the same reasons as claim 20.

Claims 24 also was rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 5,360,414 (Yarger).

Claim 24 recites subject matter that is similar to the subject matter recited in claim 1, discussed above. More particularly, claim 24 recites "an elongated access member . . . having a proximate end, a distal end and an outer wall defining a longitudinal bore extending the length of the access member; the outer wall having a window communicating with the longitudinal bore and defining a radial arc in the range of about 90 degrees to about 180 degrees around a longitudinal axis of the access member; the outer wall having a slot that extends through an entire thickness of the outer wall and communicating with the longitudinal bore, wherein the slot extends from the window to the distal end approximately parallel to the longitudinal axis of the access member."

For similar reasons as those discussed above with reference to claim 1, Yarger does not disclose or render obvious the claimed subject matter.

Claim 24 is allowable for at least the foregoing reasons.

New Claims

Claims 26 and 27 depend from claim 1 and, therefore, are allowable for at least the same reasons as claim 1.

Claim 28 recites "an access member including an outer wall defining an internal lumen, the access member having a longitudinal axis . . . an opening at the distal end of the access member, wherein the opening intersects the longitudinal axis of the access member, [and] a

window that extends through the entire thickness of the outer wall in a radial direction adjacent the distal end of the access member.”

An example of the subject matter of claim 28 is shown in Figure 1, which shows an access member 10 including an outer wall 14 defining an internal lumen 16. The access member 10 has a longitudinal axis “ α ” and an opening at the distal end 20 of the longitudinal bore 16 of the access member 10. The opening intersects the longitudinal axis “ α ” of the access member 10. A window 24 extends through the entire thickness of the outer wall 14 in a radial direction adjacent the distal end 20 of the access member 10.

The Yarger patent does not disclose or render obvious the subject matter of claim 28. For example, the distal tip 31 of Yarger's perforated suction tube 42 is rounded and sealed. The perforated suction tube 42 does not have an opening intersects its longitudinal axis at a distal end thereof. Nor would a person of ordinary skill have had any reason to modify Yarger's perforated suction tube in a manner that would have led to the claimed subject matter.

Claim 28 is allowable for at least the foregoing reasons.

Claims 29 and 30 depend from new claim 28 and, therefore, are allowable for at least the same reasons as claim 28.

Claim 31 recites “an access member including an outer wall defining an internal lumen, the access member having a longitudinal axis and proximal and distal ends, . . . an opening at the distal end of the access member, wherein the opening intersects the longitudinal axis of the access member, one and only one window in the outer wall that extends through the entire thickness of the outer wall in a radial direction and is adjacent the distal end of the access member, the window having a radial arc around the longitudinal axis between about 90 degrees and about 180 degrees, one and only slot that extends through the entire thickness of the outer wall in the radial direction, wherein the slot extends in a longitudinal direction from the window to the opening at the distal end of the access member, wherein the slot has a radial arc around the longitudinal axis that is less than the radial arc of the window.”

The Yarger patent does not disclose or render obvious the claimed subject matter. For example, the distal tip 31 of Yarger's perforated suction tube 42 does not have an opening at its distal end that intersects its longitudinal axis; instead, Yarger's distal tip is rounded and sealed. Additionally, the external lumens in Yarger's perforated suction tube 42 do not extend through the entire thickness of the outer wall in a radial direction; instead, they extend only partially through the thickness of the perforated suction tube 42. Moreover, Yarger's perforated suction tube 42 has more than one window and more than one slit. Nor would a person of ordinary skill have had any reason to modify Yarger's perforated suction tube 42 in a manner that would have led to the subject matter of claim 31.

Claim 31 is allowable for at least the foregoing reasons.

As mentioned above, claim 32 is identical to the version of claim 1 that previously was pending and, therefore, was rejected in the November 24, 2010 office action, under 35 U.S.C. §103(a) over Yarger. As discussed below, the applicant disagrees with this rejection.

Claim 32 recites "a window adjacent the distal end in communication with the internal lumen and having a radial arc ranging from about 90 degrees to about 180 degrees around the longitudinal axis." The office action concedes that Yarger does not disclose this claim feature. The office action alleges, however, that it would have been obvious to make the holes 28 in Yarger's nasogastric suction tube larger to satisfy this claim limitation, because if "a device having the claimed . . . dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device."

However, a person of ordinary skill would not have considered it obvious to modify Yarger in the manner that the examiner asserts would have been obvious due to concerns that changing the size of the hole 28 would potentially allow enough organ wall or body tissue to be sucked into the holes 28 to block the holes 28 and the ends of the lumens 26 that are in communication with the holes 28. This would defeat one of the primary purposes of the Yarger device (i.e., to avoid blockages).

Thus, a person of ordinary skill would not have considered the proposed modifications to be desirable at all, certainly not obvious.

Claim 32 should be allowable for at least the foregoing reasons.

Conclusion

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

The extension of time fee and excess claims fee are being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any additional charges or credits to Deposit Account No. 06-1050, referencing Docket No. 27527-0039001.

Respectfully submitted,

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